

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. (Currently Amended) A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising about 1% (w/v) propofol, and an excipient comprising Poloxamer 188, and one or more additional excipients, in combination with excipients, said excipients including:
7% to 9% (w/v) poloxamer component consisting essentially of Poloxamer 188;
2% to 4% (w/v) polyethylene glycol; and
not more than 1% (w/v) lipid
wherein said excipients comprise not more than 15% (w/v) of said composition and said composition is stored in a container having a means for dispensing the composition, and wherein the total propofol degradants of the solution when maintained at 25 °C, 40 °C, or 60 °C for 4 weeks are present in an amount of less than 5% (w/v) of said composition.

2 - 5. (Canceled)

6. (Currently Amended) The composition of Claim 21, wherein:

a) said composition comprises poloxamer 188, said polyethylene glycol comprises polyethylene glycol 400, and propylene glycol;

(i) wherein said composition excipients further comprise one or more compounds selected from the group consisting of citric acid, disodium edetate, metabisulfate, benzyl alcohol, propylene glycol, an antioxidant, a preservative, an antimicrobial agent, and a microbicide;

b) said composition comprises poloxamer 188 and polyethylene glycol 400;

(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;

~~c) said composition comprises poloxamer 188 (8% w/v), polyethylene glycol 400 (4% w/v), and propylene glycol (1% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~d) said composition comprises poloxamer 188 (8% w/v), polyethylene glycol 400 (3% w/v), and propylene glycol (1% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~e) said composition comprises poloxamer 188 (8% w/v), polyethylene glycol 400 (2% w/v), and propylene glycol (1% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~f) said composition comprises poloxamer 188 (8% w/v) and polyethylene glycol 400 (3% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~g) said composition comprises poloxamer 188 (8% w/v) and polyethylene glycol 400 (2% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~h) said composition comprises poloxamer 188 (8% w/v) and polyethylene glycol 400 (4% w/v);~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~i) said composition comprises poloxamer 188 (7% w/v), polyethylene glycol 400 (3% w/v), and propylene glycol (1% w/v);~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~j) said composition comprises poloxamer 188 (7% w/v) and polyethylene glycol 400 (3% w/v);~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~i) said composition comprises poloxamer 188 (7% w/v), polyethylene glycol 400 (2% w/v), and propylene glycol (1% w/v);~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~j) said composition comprises poloxamer 188 (7% w/v) and polyethylene glycol 400 (2% w/v)~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~k) said composition comprises poloxamer 188 (6% w/v), polyethylene glycol 400 (4% w/v), and propylene glycol (1% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;~~

~~l) said composition comprises poloxamer 188 (6% w/v), polyethylene glycol 400 (4% w/v), and propylene glycol (2% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide;
or~~

~~m) said composition comprises poloxamer 188 (9% w/v) and polyethylene glycol 400 (2% w/v):~~

~~(i) wherein said composition further comprises one or more compound selected from citric acid, disodium edetate, metabisulfate, benzyl alcohol, an antioxidant, a preservative, an antimicrobial agent, or a microbicide.~~

7. (Canceled)

8. (Previously Presented) The composition of Claim 1, wherein:

- a) said composition has a particle size diameter of between 25 and 200 nm;
- b) said composition has a particle size diameter of between 50 and 100 nm; or
- c) said composition forms particles of similar particle size.

9. (Previously Presented) The composition of Claim 1, wherein:

- a) said composition does not support microbial growth;
- b) said composition is microbicidal; or

c) said composition is sufficient for no more than a 10-fold increase in growth, of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027 or *Candida albicans* ATCC 10231 for at least 24 hours.

10. (Currently Amended) The composition of Claim 1, wherein:

a) said composition is functionally ~~bioequivalent~~bioequivalent to commercial lipid based anesthetic products:

(i) wherein said ~~bioequivalence~~bioequivalence is demonstrated in dogs;

(ii) wherein said ~~bioequivalence~~bioequivalence is demonstrated in humans;

or

b) said composition has a red blood cell blood plasma partition coefficient greater than that of commercial lipid based anesthetic products:

(i) wherein said partition coefficient for said composition is between about 2 and 4.

11. (Previously Presented) The composition of Claim 1, further comprising:

a) an acid;

b) a base;

c) a local anesthetic;

d) a second general anesthetic;

e) an antimicrobial agent;

f) a surfactant;

g) a tonicity modifier;

(i) wherein said tonicity modifier is glycerol;

h) a pH modifier; or

j) a second, third, fourth, fifth, or sixth excipient.

12. (Currently Amended) The composition of Claim 1, wherein said composition is substantially free of:

~~a. a lipid, a long chain fatty acid, triacylglycerol, or glycerol ester;~~

~~b. a. an antimicrobial agent; or~~

~~c. b. a preservative.~~

13.-24. (Canceled)

25. (New) A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising about 1% (w/v) propofol in combination with excipients, said excipients including:

7% to 9% (w/v) poloxamer component consisting essentially of Poloxamer 188;

2% to 4% (w/v) polyethylene glycol;

0% to 1% (w/v) propylene glycol; and

not more than 1% (w/v) lipid

wherein said excipients comprise not more than 15% (w/v) of said composition.

26. (New) The composition of Claim 25, wherein said excipients comprise: 8% (w/v) Poloxamer 188; 3% (w/v) polyethylene glycol 400; and 1% (w/v) propylene glycol.